

## Research Staff Training- RPG- 01

### Guideline

#### Purpose

This document is intended to provide guidance to clinical investigators and staff conducting clinical investigations for tracking and documenting research staff training and education. By ensuring research staff are adequately trained the PI can help to make sure that:

- 1) Human subjects are protected.
- 2) The study protocol is being followed accurately and consistently between staff and over time.
- 3) Quality assurance procedures are being adhered to.
- 4) The investigator, who is ultimately responsible for conduct of his/her clinical investigation, has shown due diligence by documenting training of study staff to which he/she has delegated study responsibilities to.
- 5) Study staff is knowledgeable and trained on study procedures before participating in the study.
- 6) Best practices for clinical research are adhered to.

#### Definitions

**CITI (Collaborative Institutional Training Initiative):** a web-based training program in human subjects protections. Material was developed through a collaboration of experts from ten institutions and includes modules focused on human subjects protections related to biomedical, social, and behavioral issues.

## Procedure

### Previous Training

Research staff should be hired based on the requirements listed in the job document for the research position. Demonstration of prior education as well as years and types of experience in those areas should be listed in the candidate's curriculum vitae. For positions that require clinical/medical tasks that have licensing or certification requirements (such as a medical or nursing license).

### Requirements for Conducting Research at Children's Hospital Boston

All clinical investigators and research staff must complete CITI training before they are allowed to participate in an IRB approved clinical investigation. Completion of CITI training is a basic requirement for anybody conducting research at Children's Hospital Boston. Although CITI training offers a basic overview on human subjects protection it should not be considered comprehensive training on general competencies for research staff, and does not include any education or training on specific study protocols. In addition, CHERP (the on-line system for the IRB) has a separate computer-based learning module this is also required.

Investigators: All new and transfer investigators are required to meet with the Education and Quality Improvement Program (EQUIP) prior to approval of the first IRB protocol where they are listed as the Principal Investigator.

Additional educational opportunities for clinical investigators, research coordinators, and other research staff are offered through the Clinical Research Center. See CRC Education Core offerings for current classes and enrollment.

It is recommended that all research coordinators attend the "Orientation for New Study Coordinators" program offered through the Clinical Research Center. Second, all coordinators are asked to attend a clinical orientation (heights/weights, MOAB and SBAR) that is called "Clinical Research Study Coordinator Orientation"; sign-up occurs in Net Learning and is taught by Patient Services. Third, all new coordinators will work with the supervisor on various competencies during their first year of employment.

### Study Specific Training

Prior to conducting a clinical investigation, all investigators and research staff should be trained on the study protocol as well as their individual documented study-specific responsibilities. Training for a multi-center trial, or a trial with a sponsor other than the clinical investigator, is through a clinical investigator meeting at the beginning of the trial. The hospital now conducts an Investigational New Drug (IND) or Investigational Device exception (IDE) Review group (IIRG) meeting for those protocols where there is an IND/IDE. The current contact for this is Susan Kornetsky and Erik Halvorsen. For single-center trials, individual training with the study staff on the specific delegated task may be more appropriate. Study-specific training should be conducted for everybody on the clinical investigation who participates in some aspect of the

research, including research coordinators/assistants, research nurses, and bedside nurses and other clinical staff performing research study-specific procedures. Training documentation should be maintained by the study team.

In cases where somebody other than the PI is training the staff on research procedures, the PI is responsible for ensuring that training is adequate and is documented.

Periodic re-training of the same study staff may also be required for longitudinal studies to prevent drift.

### **Documentation**

Study-specific training logs should be maintained for all research staff working on the projects. Documentation should include the topics covered and be signed by the staff member trained as well as the person who conducted the training. It is also recommended that the Principal Investigator sign off on the training log to acknowledge the training was completed before the staff began work on the clinical investigation. For FDA regulated trials, the training logs should be stored in the study regulatory binder (see Related Content from EQUIP below).

## **Related Content**

- [\*EQuIP Training Log Guidance\*](#)
- [\*EQuIP Training Log v.1\*](#)
- [\*EQuIP Training Log v.2\*](#)

# References

Document Attributes					
<b>Title</b>	Research Staff Training – RPG-01				
<b>Author</b>	Adam Simmons, MPH, CCRC / Sarah Krathwohl, MPH	<b>Date of Origin</b>	June 2011		
<b>Reviewed/Revised by</b>	Ellis Neufeld, MD, PhD	<b>Dates Reviewed/Revised</b>	08/28/13		
<b>Copyright</b>	©Boston Children’s Hospital, 2013	<b>Last Modified</b>	08/28/2013		
<b>Approved</b>	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> <u><b>SIGNATURE ON FILE</b></u>                      Stavroula Osganian, MD, ScD, MPH                      Co-Chief, Clinical Research Center                 </td> <td style="width: 50%; border: none; vertical-align: top;"> <u><b>SIGNATURE ON FILE</b></u>                      Ellis Neufeld, MD, PhD                      Associate Chief, Division of Hematology/Oncology                 </td> </tr> </table>			<u><b>SIGNATURE ON FILE</b></u> Stavroula Osganian, MD, ScD, MPH Co-Chief, Clinical Research Center	<u><b>SIGNATURE ON FILE</b></u> Ellis Neufeld, MD, PhD Associate Chief, Division of Hematology/Oncology
<u><b>SIGNATURE ON FILE</b></u> Stavroula Osganian, MD, ScD, MPH Co-Chief, Clinical Research Center	<u><b>SIGNATURE ON FILE</b></u> Ellis Neufeld, MD, PhD Associate Chief, Division of Hematology/Oncology				

ICH Guidelines for Good Clinical Practice 4.2.4

Guidance for Industry: Protecting the Rights, Safety, and Welfare of Study Subject-Supervisory Responsibilities of Investigators (Draft Version May 2007) CHB Office of Clinical Investigations. [www.childrenshospital.org/research/irb](http://www.childrenshospital.org/research/irb)

**Disclaimer:** Should Hospital and CRC policies conflict, Hospital policy will supersede CRC policy in all cases.